REMARKS

In this Response, no claims have been added and no claims have been cancelled. Claims 34 and 43 have been amended. Claim 34 has been amended to correct a minor typographical error. The amendment of claim 43 is discussed in detail below. No new matter has been added. Amendment of these claims is made without prejudice and is not to be construed as a dedication to the public of any subject matter.

Disposition of Present Claims

Applicants first request clarification regarding the status of the claims currently pending in the Application. There appears to be somewhat of an inconsistency between the Applicants' understanding of the status of these claims, and the status that was set forth in the Office Action. Specifically, the "Disposition of Claims" section on the face of the Office Action Summary indicates that claims 10, 13, 15-25, 28, 29, and 34-43 are pending, and that claims 41 and 42 have been withdrawn from consideration.

It is not the Applicants' understanding that claims 41 and 42 have been withdrawn from consideration. Similarly, it is not the Applicants' understanding that claim 21 is currently pending. Applicants' understanding is that claims 10, 13, 15-20, 22-25, 28-29, and 34-43 are currently under consideration, and Applicants request confirmation that these are the claims being considered.

Rejections under 35 U.S.C. §102(b)

Claims 10 and 13

Claims 10 and 13 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,169,638 to Dennis *et al.* ("Dennis"). In support of this rejection, the Office Action states that "Dennis et al. Teach a powder containing an active comprising up to 45% alginic acid and up to 35% gelling agent (abstract). Hydroxypropylmethyl cellulose is disclosed (column 5 line 31). Up to 7% active is specified (column 4 lines 17-19)." (*see* Office Action, page 2).

Applicants disagree with this rejection. To be anticipatory, a reference must teach each and every element of the claimed invention, *see* MPEP §2141. That is, a claim is anticipated only if each and every element is described, either expressly or inherently, in a single prior art reference. *Id* (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The Office Action fails to set forth the anticipation of claims 10 and 13. Specifically, the Office Action fails to identify how each and every element of claims 10 and 13 are described in Dennis.

In particular, claim 10, from which claim 13 depends, recites an "implant" comprising a "biodegradable polymer," which is "degraded at the site of implantation." In addition, claim 10 recites that the implant releases a first therapeutically active agent "within a therapeutic dosage which does not vary by more than about 100% for a period of at least about 3 days after implantation." The statements set forth in the Office Action are insufficient to establish how each of these elements is set forth in Dennis.

For instance, the Office Action makes no showing of, and provides no support for, where Dennis teaches a biodegradable polymer. In fact, nowhere does the specification of Dennis refer to a "biodegradable polymer." Similarly, the Office Action fails to identify where Dennis discloses an "implant" as described in Applicants' specification and recited by claims 10 and 13. Indeed, the formulations of Dennis are not "implants," but are instead buoyant controlled release formulations for oral administration. Not only does Dennis fail to teach or disclose an "implant," he also fails to teach or disclose an implant that releases a therapeutically active agent "within a therapeutic dosage which does not vary by more than 100% for a period of at least about 3 days after implantation," as recited by claims 10 and 13.

Because Dennis fails to teach or disclose each and every element of claims 10 and 13, rejections under 35 U.S.C §102(b) cannot be maintained. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Rejections under 35 U.S.C. §102(e)

Claims 34-40

Claims 34-40 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,656,297 to Bernstein *et al.* ("Bernstein"). In support of this rejection, the Office Action states that "Bernstein et al teaches soluble cationic release modifiers in matrices of biocompatible polymers (abstract, column 5 lines 27-35). Polylactide glycoside is disclosed (column 3, line 62). 20-30% modifier is disclosed (column 5 lines 10-12). Steroids are specified (column 4 line 34). Up to 50% active is disclosed (column 4 line 51). Biodegradable polymers are specified (column 3 line 56). Microspheres are disclosed (column 12 line 8)."

Again, Applicants disagree with this rejection. As noted above, anticipation requires a showing that each and every element has been described in a prior art reference. The Office Action fails to establish such an anticipatory showing. That is, Bernstein fails to teach or describe each and every element of independent claims 34 and 39, from which the remaining rejected claims depend.

For instance, claim 34, from which claims 35-38 depend, recites an implant that is degraded at a site of implantation "within the ocular region." Similarly, claim 39, from which claims 41-43 depend (all of which Applicants submit are currently pending) recites an implant that is "sized for implantation within the ocular region." Bernstein fails to teach or suggest these elements.

Bernstein discloses a biocompatible polymeric matrix having a metal cation component dispersed therein. Notably absent from Bernstein's laundry list of suggested methods of administering his matrix, is intraocular administration, or administration within the ocular region. At col. 7, line 66- col. 8, line 7, Bernstein states that "[t]he composition of this invention can be administered to a human, or other animal, by injection and/or implantation subcutaneously, intramuscularly, intraperitoneally, intradermally, intravenously, intraarterially or intrathecally; by administration to mucosal membranes, such as intranasally or by means of a suppository...," however, nowhere does Bernstein teach that his matrix is degraded at a site within the ocular

region. Similarly, Bernstein fails to teach that his matrix may be sized to be implanted within the ocular region.

Accordingly, the rejection of claims 34-40 under 35 U.S.C. §102(e) in view of Bernstein are improper and should be withdrawn.

Rejections under 35 U.S.C. §112, ¶ 1

Claim 43

Claim 43 stands rejected under 35 U.S.C. §112, ¶ 1 as allegedly containing subject matter that was not described in the specification in a way to reasonably convey that the Applicants had possession of the claimed invention at the time it was filed. Specifically, the Office Action asserts that "Nowhere in the specification do applicants disclose the claimed range of 2-4 microns."

Applicants have amended claim 43, rendering this rejection moot. Specifically, claim 43 has been amended to recite that the microspheres have a diameter in the range of about 2μm to about 3mm. Support for this amendment may be found in the specification on page 12, lines 20-21. No new matter has been added. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §112, ¶1 be withdrawn.

Allowable Subject Matter

Claims 19, 20, 22-25, 28, 29, and 15-18

The Office Action notes that claims 19, 20, 22-25, 28, and 29 are allowed, and that claims 15-18 have been objected to as being dependent upon a rejected base claim. While Applicants note that claims 15-18 would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims, Applicants have not so amended these claims. Instead, Applicants submit that in view of the above Amendments and Remarks, all pending claims are allowable.

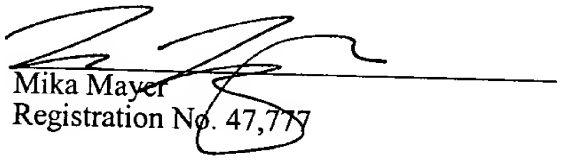
Conclusion

Applicants have responded to each matter of substance raised in the Office Action and submit that the case is in condition for allowance. If the Examiner has any requests, questions, or suggestions, or believes that a phone call may help expedite the prosecution of this case, he is invited to contact Applicants' agent at the number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 440882001201. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: August 14, 2003

By: 

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